Avoidance behavior after mild traumatic brain injury: psychological treatment based on cognitive behavioral therapy. Four single case studies.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28396

Source
Nationaal Trial Register

Brief title
Brain Exposure

Health condition

mild traumatic brain injury (mTBI) and post concussion syndrome (PCS)

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Zuyderland Medisch Centrum and Research en Innovatiefonds

Intervention

Outcome measures

Primary outcome

Post concussion symptoms (Rivermead post concussion questionnaire (RPQ) + individualized visual analog scale for the three most common PCS symptoms (VAS))

Secondary outcome

Fear (Fear of Mental Activity Scale (FMA)), catastrophizing (Post-Concussion Symptoms Catastrophizing Scale (PCS-CS), social participation and quality of life (Utrecht Scale for Evaluation of Rehabilitation-Participation-restriction scale (User-P)).

Study description

Background summary

Rationale: Traumatic brain injury (TBI), of which the vast majority is considered mild (mTBI), poses a major global health issue with its high prevalence and subsequently societal costs. The many studies on natural recovery after mTBI show a consistent picture of complete recovery at the latest 3 months after injury. However, a substantial group of patients (15-47 percent) experience persistent symptoms >3 months after their injury. This is often referred to as post-concussion syndrome (PCS), a syndrome that is not formally recognized, and can interfere with activities of daily living such as return to work. The cause of PCS is not well understood and an effective and scientifically proven treatment model is still lacking. The fear avoidance model provides a biopsychosocial explanation for PCS. This model suggests that it is not the severity of the injury, but a disease process of extended catastrophic thinking about the initial symptoms and fear avoidance behavior that will lead to persistence of symptoms. This model is well-validated in patients with several bodily distress syndromes and several of these syndromes have been successfully treated with cognitive behavioural therapy (CBT) based on principles of graded exposure. This study will investigate if exposure-based CBT to tasks, activities and environments that elicit fear and avoidance behaviour results in a reduction of PCS in patients with mTBI. In addition, we will investigate if exposure therapy improves social participation and quality of life.
Objective: Studying the effect of cognitive behavioral therapy based on principles of graded exposure on PCS, social participation and quality of life in patients with mTBI.
Study design: SCED series (single case experimental design).
Study population: mTBI patients (>17 years old) seeking help for PCS referred to a psychologist by the neurologist or physiatrist of Zuyderland Medical Centre.
Intervention (if applicable): 10-12 session of exposure-based CBT to tasks, activities and environments that elicit fear and are avoided.
Main study parameters/endpoints: Post concussion symptoms, fear, catastrophizing, social participation and quality of life. Questionnaires: Rivermead post concussion questionnaire (RPQ), Post-Concussion Symptoms Catastrophizing Scale (PCS-CS), Fear of Mental Activity Scale (FMA), Individualized visual analog scale for the three most common PCS symptoms (VAS), Utrecht Scale for Evaluation of Rehabilitation-Participation-restriction scale (User-P).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden and risks associated with participation are considered to be

neglicible and fall within the normal and described risk factors for CBT. Patients will have to come to the hospital 10-12 times for the individual therapy sessions as part of their regular treatment, which will also include regular homework assignments. In addition they have to fill in questionnaires in the context of scientific research. There is no physical or physiological discomfort associated with participation. It is known that symptoms can initially increase when treatment is started. Ultimately, a reduction of post-concussion symptoms is expected. The participants will be informed that they are free to end their participation to the study at any time.

Study objective

The primary objective:
Does exposure-based CBT reduce PCS in patients with mTBI after treatment completion and at three months follow up?

The secondary objectives:
- Does exposure-based CBT increase social participation and quality of life in mTBI patients with PCS after treatment completion and at three months follow up?
- Is the reduction of PCS accompanied by reduced fear and reduced catastrophizing?
- Is the treatment protocol experienced as effective and feasible by the patients and practitioners?

Study design

T0, T1, T2 and T4

Intervention

cognitive behavioral based exposure therapy

Contacts

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Eligibility criteria

Inclusion criteria

- Received diagnosis mTBI according the WHO criteria (Cassidy et al., 2004)
- Seeks help for chronic symptoms associated with PCS
- Referred for and capable of receiving monodisciplinary psychological treatment
- The mTBI was sustained at a minimum of 3 months before participating in the study
- High level of fear avoidance and catastrophizing (Fear of Mental Activity scale cut-off >15, Post-Concussion Symptoms Catastrophizing Scale cut-off >8). These measurements are part of the intake procedure of the psychologist.
- >17 years old
- Fluent in Dutch
- In possession of an email-account and a device with internet connection
- No change in medication regime (i.e. psychopharmacology, such as antidepressants) for the duration of the study and four weeks prior to the beginning of the study

Exclusion criteria

- History of severe neurological disorders or brain damage
- History of psychiatric disorders for which specialized mental health treatment was necessary.
- History of exposure treatment for the consequences of mTBI
- Legal procedure related to the PCS
- No informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	22-02-2021
Enrollment:	4
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9284
Other	METC Zuyderland : METCZ20210026

Study results